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Assessment of the effect of perindopril orodispersible tablet at the dose of 0.150 mg/kg /day on muscular and myocardic functions in the early stage of Duchenne Muscular Dystrophy: a two-year, double-blind, randomised, placebo-controlled study

Submission date
16/01/2009

Recruitment status
No longer recruiting

Registration date
16/02/2009

Overall study status
Completed

Last Edited
21/04/2020

Condition category
Nervous System Diseases

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol
Not provided at time of registration and not expected to be available in the future

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number
2008-003856-32

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
CL3-90652-004

Study information

Scientific Title
Assessment of the effect of perindopril orodispersible tablet at the dose of 0.150 mg/kg/day on muscular and myocardic functions in the early stage of Duchenne Muscular Dystrophy: a two-year, double-blind, randomised, placebo-controlled study

Study objectives
Effect on peripheral muscular function.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics approval was obtained before recruitment of the first participants

Study design
Double-blind randomised placebo-controlled study

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details to request a patient information sheet

Health condition(s) or problem(s) studied
Duchenne Muscular Dystrophy

Interventions
Perindopril orodispersible tablet 0.150 mg/kg/day versus placebo for two years.

Intervention Type
Drug

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Perindopril

Primary outcome measure
Six-minute walking distance, evaluated each 6 months

Secondary outcome measures
1. Other muscular tests
2. Echocardiography
3. Respiratory function assessment

Evaluated at inclusion visit and end-of-study visit

Overall study start date
01/02/2009

Completion date
30/09/2012

Eligibility

Key inclusion criteria
Children, less than 7 years old with Duchenne Muscular Dystrophy and able to complete a 6-minute walk test

Participant type(s)
Patient

Age group
Child

Upper age limit
7 Years

Sex
Male

Target number of participants
40

Total final enrolment
40

Key exclusion criteria
1. Long term treatment with corticoids
2. Treatment with ACE inhibitors or AT1 antagonists

Date of first enrolment
01/02/2009

Date of final enrolment
30/09/2012

Locations

Countries of recruitment
France

Study participating centre
Groupe hospitalier Necker - Enfants Malades
Paris Cedex 15
France
75743

Sponsor information

Organisation
Institut de Recherches Internationales Servier (France)

Sponsor details
50 rue Carnot
Suresnes
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92284

Sponsor type
Industry

Website
http://www.servier.com/

ROR
https://ror.org/034e7c066

Funder(s)

Funder type
Industry

Funder Name
Institut de Recherches Internationales Servier (France)

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Basic results				No	No
Basic results			21/04/2020	No	No